

Remarks

Claims 84-93 and 123 are pending in the present application. Claim 84 is provisionally rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over co-pending application 10/152,106.

In addition, Claims 84-93 and 123 are provisionally rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over co-pending application 10/652,962.

Further, Claims 86-93 and 123 are rejected under 35 USC 112, second paragraph.

Additionally, Claims 84-93 and 123 are rejected as being anticipated, or alternately as obvious, over US Patent No. 6,451,990 by Bayod Jasanada et al. or US Patent No. 6,268,489 by Allen et al.

Claim 85 was amended to more clearly reflect that the solvent used to make "form O" azithromycin was n-butanol.

Claims 86-93 are amended to further clarify the recitation of the azithromycin forms recited therein.

No new matter has been added by this amendment.

The Examiner's rejections of pending Claims 84-93 and 123 shall now be addressed in the order made by the Examiner.

Provisional Rejection of Claim 84 Under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The Examiner has provisionally rejected Claim 84, under the doctrine of obviousness-type double patenting, over claim 32 of co-pending Application No. 10/152,106. The Examiner states that though the conflicting claims are not identical, that they are not patentable distinct

because the claim of the co-pending application is not limited to pure azithromycin sesquihydrate but encompasses the mixtures claimed in Claim 84.

The Examiner's argument is incorrect as the Examiner has confused non-statutory obviousness-type double patenting with domination.

As the present Application and co-pending Application No. 10/152,106 were filed upon the same date, the test for determining if this is non-statutory obviousness-type double patenting is a one-way obviousness test. Specifically, the test would be whether the invention described in Claim 84 of the present Application is obvious in view of claim 32 of co-pending Application No. 10/152,106.

Claim 32 of co-pending Application No. 10/152,106 recites crystalline azithromycin sesquihydrate form G.

Claim 84 of the present Application recites an azithromycin mixture comprising azithromycin dihydrate and one or more hydrate/solvates of azithromycin or azithromycin sesquihydrate.

Contrary to the Examiner's statement, the invention of present Claim 84 is not obvious in view of co-pending claim 32 because claim 32 does not disclose or suggest any mixture of azithromycin dihydrate with any other hydrate or solvate of azithromycin. Further, Claim 32 does not disclose or suggest any mixture of azithromycin sesquihydrate with azithromycin dihydrate.

Rather, claim 32 only dominates the present Claim 84 in the embodiment when the azithromycin dihydrate mixture also contains azithromycin sesquihydrate. Domination, in itself, does not negate patentability (See *In re Kaplan*, 789 F.2d at 1577-78 and MPEP 804).

Therefore, the Claim 84 is not properly rejected for judicially-created obviousness-type double patenting over Claim 84 of co-pending Application No. 10/152,106.

Provisional Rejection of Claims 84-93 and 123 Under the
Judicially Created Doctrine of Obviousness-Type Double
Patenting

The Examiner has provisionally rejected Claims 84-93 and 123, under the doctrine of obviousness-type double patenting, over claims 1-7, 79-83, 94-96 and 123-124 of co-pending Application No. 10/652,962. The Examiner states that though the conflicting claims are not identical, that they are not patentable distinct because the claims of the co-pending application are not limited to isolated compounds but encompasses mixtures claimed.

Claims 84-86 and 123

The Examiner's argument is incorrect as the Examiner has confused non-statutory obviousness-type double patenting with domination.

As the present Application and co-pending Application No. 10/652,962 were filed upon the same date, the test for determining if this is non-statutory obviousness-type double patenting is a one-way obviousness test. Specifically, the test would be whether the invention described in Claims 84-86 and 123 of the present Application are obvious in view of claims 1-7, 79-83, 94-96 and 123-124 of co-pending Application No. 10/652,962.

Claims 1-7, 79-83, 94-96 and 123-124 of co-pending Application No. 10/652,962 relate to crystalline cyclohexane, tetrahydrofuran and tert-butyl methyl ether solvates of azithromycin.

Claims 84-86 and 123 of the present Application relate to azithromycin mixture comprising azithromycin dihydrate and one or more hydrate/solvates of azithromycin or azithromycin sesquihydrate.

Contrary to the Examiner's statement, the invention of present Claims 84-86 is not obvious in view of co-pending claims 1-7, 79-83, 94-96 and 123-124 because these co-pending claims do not disclose or suggest any mixture of azithromycin dihydrate with any other hydrate or solvate of azithromycin. Further, these co-pending claims do not disclose or suggest any mixture of azithromycin sesquihydrate with azithromycin dihydrate.

Rather, these co-pending claims only dominate present Claims 84-86 and 123 in the embodiments when the azithromycin dihydrate mixture also contains cyclohexane, tetrahydrofuran or tert-butyl methyl ether solvates of azithromycin. However, domination, in itself, does not negate patentability (See *In re Kaplan*, 789 F.2d at 1577-78 and MPEP 804).

Therefore, the Claims 84-86 and 123 are not properly rejected for judicially-created obviousness-type double patenting over Claims 1-7, 79-83, 94-96 and 123-124 of co-pending Application No. 10/652,962.

Claims 87-93

Applicants' invention, as recited in Claims 87-93, relates to a mixture of azithromycin dihydrate with azithromycin ethanol solvate form F, azithromycin sesquihydrate form G, azithromycin propylene glycol solvate form H, azithromycin n-propanol solvate form J or azithromycin isopropanol solvate form M. However, Claims 1-7, 79-83, 94-96 and 123-124 of co-pending Application No.

10/652,962 do not disclose or suggest any of the aforementioned azithromycin solvates or hydrates. Further, Claims 1-7, 79-83, 94-96 and 123-124 of co-pending Application No. 10/652,962 do not disclose or suggest mixtures of azithromycin dihydrate with any of the aforementioned azithromycin solvates or hydrates.

Therefore, mixtures of azithromycin dihydrate, with any of azithromycin ethanol solvate form F, azithromycin sesquihydrate form G, azithromycin propylene glycol solvate form H, azithromycin n-propanol solvate form J or azithromycin isopropanol solvate form M, are not properly rejected for judicially-created obviousness-type double patenting over Claims 1-7, 79-83, 94-96 and 123-124 of co-pending Application No. 10/652,962.

Rejection of Claims 86-93 and 123

Under 35 USC 112, Second Paragraph

The Examiner has rejected pending claims 86-93 and 123 under 35 USC 112, second paragraph, as being indefinite. Specifically, the Examiner stated that the terms "form D", "form F", "form G", "form H", "form J", "form M", "form O", "form Q", "form R" and "form A" are not art recognized terms. Further, the Examiner stated that there was no antecedent basis in Claim 86 for the term "form A" which was recited in Claims 87-93.

Responsive to the Examiner's statements, Claims 86-93 have been amended to further clarify the terms "form D", "form F", "form G", "form H", "form J", "form M", "form O", "form Q", "form R" and "form A".

Therefore, the present rejection under 35 USC 112, second paragraph, is now moot.

Rejection of Claims 84-93 and 123 Under 35 USC 102(a)
Or Alternately Under 35 USC 103(a)

The Examiner has rejected all pending claims under 35 USC 102(a) as being inherently anticipated by, or in the alternative, under 35 USC 103(a) as being obvious in view of US Patent No. 6,451,990 (hereinafter "Bayod Jasanada et al.") or US Patent No. 6,268,489 (hereinafter "Allen et al.").

Bayod Jasanada et al.

The Examiner stated that Bayod Jasanada et al. disclose the preparation of azithromycin dihydrate from acetone/water or from tert-butanol/water. The Examiner states that the formation of a mixture of azithromycin dihydrate and solvates of azithromycin with acetone or butanol would have been inherent in such a process.

Further, the Examiner stated that asserted that the formation of a mixture of azithromycin dihydrate and solvates of azithromycin with acetone or butanol would have been inherent in such a process.

Claims 84-85 and 123

Applicants' invention, as recited in Claims 84-85 and 123, relates to a mixture of azithromycin dihydrate and one or more hydrate/solvates of azithromycin.

Contrary to the Examiner's assertion, Bayod Jasanada et al. do not disclose or suggest a mixture of azithromycin dihydrate and one or more hydrate/solvates of azithromycin. Specifically, Bayod Jasanada et al. neither disclose nor suggest that the crystalline azithromycin formed by recrystallization from tert-butanol or acetone, by the process described therein, contains a tert-butanol solvate of azithromycin. Rather, Bayod Jasanada et al. state that

the product formed by recrystallization of azithromycin from tert-butanol, or acetone, was crystalline azithromycin dihydrate. Furthermore, the Examiner cites no other references which teach that such a tert-butanol solvate, or acetone solvate, would inherently be formed by this process. Therefore, the Examiner has made a presumption, without a stated basis, that the mere use of a solvent in a process, for recrystallizing azithromycin to form azithromycin dihydrate, would inherently produce a solvate of said recrystallization solvent.

Thus, mixtures of azithromycin dihydrate, with azithromycin hydrate/solvates are neither anticipated by or obvious over Bayod Jasanada et al.

Claims 86-93

Applicants' invention, as recited in Claims 86-93, relates to a mixture of azithromycin dihydrate with azithromycin cyclohexane solvate form D, azithromycin ethanol solvate form F, azithromycin sesquihydrate form G, azithromycin propylene glycol solvate form H, azithromycin n-propanol solvate form J, azithromycin isopropanol solvate form M, azithromycin n-butanol solvate form O, azithromycin tetrahydrofuran solvate form Q or azithromycin tert-butyl methyl ether solvate form R. However, Bayod Jasanada et al. do not disclose or suggest any of the aforementioned azithromycin solvates or hydrates. Further, Bayod Jasanada et al. do not disclose or suggest mixtures of azithromycin dihydrate with any of the aforementioned azithromycin solvates or hydrates.

Therefore, mixtures of azithromycin dihydrate, with any of azithromycin cyclohexane solvate form D, azithromycin ethanol solvate form F, azithromycin

sesquihydrate form G, azithromycin propylene glycol solvate form H, azithromycin n-propanol solvate form J, azithromycin isopropanol solvate form M, azithromycin n-butanol solvate form O, azithromycin tetrahydrofuran solvate form Q or azithromycin tert-butyl methyl ether solvate form R, are neither anticipated by or obvious over Bayod Jasanada et al.

Allen et al.

The Examiner also stated that Allen et al. disclose the preparation of azithromycin dihydrate from tetrahydrofuran and a hydrocarbon. The Examiner asserted that the formation of a mixture of azithromycin dihydrate and a solvate of azithromycin with tetrahydrofuran would have been inherent in such a process.

Claims 84-86 and 123

Applicants' invention, as recited in Claims 84-85 and 123, relates to a mixture of azithromycin dihydrate and one or more hydrate/solvates of azithromycin.

Contrary to the Examiner's assertion, Allen et al. do not disclose or suggest a mixture of azithromycin dihydrate and one or more hydrate/solvates of azithromycin. Specifically, Allen et al. neither disclose nor suggest that the crystalline azithromycin formed by recrystallization from tetrahydrofuran, by the process described therein, contains a tetrahydrofuran solvate of azithromycin. Rather, Allen et al. state that the product formed by recrystallization of azithromycin from tetrahydrofuran was crystalline azithromycin dihydrate. Furthermore, the Examiner cites no other references which teach that such a tetrahydrofuran solvate would inherently

be formed by this process. Therefore, the Examiner has made a presumption, without a stated basis, that the mere use of a solvent in a process, for recrystallizing azithromycin to form azithromycin dihydrate, would inherently produce a solvate of said recrystallization solvent.

Thus, mixtures of azithromycin dihydrate, with azithromycin hydrate/solvates are neither anticipated by or obvious over Allen et al.

Claims 87-93

Applicants' invention, as recited in Claims 87-93, relates to a mixture of azithromycin dihydrate with azithromycin ethanol solvate form F, azithromycin sesquihydrate form G, azithromycin propylene glycol solvate form H, azithromycin n-propanol solvate form J or azithromycin isopropanol solvate form M. However, Allen et al. do not disclose or suggest any of the aforementioned azithromycin solvates or hydrates. Further, Allen et al. do not disclose or suggest mixtures of azithromycin dihydrate with any of the aforementioned azithromycin solvates or hydrates.

Therefore, mixtures of azithromycin dihydrate, with any of azithromycin ethanol solvate form F, azithromycin sesquihydrate form G, azithromycin propylene glycol solvate form H, azithromycin n-propanol solvate form J or azithromycin isopropanol solvate form M, are neither anticipated by or obvious over Allen et al.

Conclusion

In view of the above, Applicants respectfully submit that the Examiner's rejections, under the judicially

created doctrine of obviousness-type double patenting, 35 USC 112, second paragraph, USC 102(a) and 35 USC 103(a) of pending Claims 84-93 and 123, as amended, are not proper. Therefore, Applicants respectfully request that these rejections of Claims 84-93 and 123, as amended, be withdrawn. Applicants further request that a notice of allowance be issued for pending Claims 84-93 and 123.

Respectfully Submitted:

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